REMARKS

Claims 1-59 are pending in the present application. Claims 23-25 have been withdrawn from consideration due to a Restriction Requirement asserted by the Examiner. Claims 1, 26, 11, 12, 19, 35, 36, 39, 43, 52, 53, and 56 have been amended herewith.

Claims 1, 26, and 43 have been amended to further define the invention. Specifically, these claims have been amended to recite a "carrier polymer" and that the "inclusion complex is incorporated into the carrier polymer." Support for these amendments can be found in the specification at, *inter alia*, page 9, line 25; page 11, lines 20-21; page 15, lines 8-23; page 16, lines 18-19 and lines 23-25; and page 17, line 25 to page 21, line 18.

Claims 11, 12, 35, 36, 52, and 53 have been amended to correct a typographical error by deleting the term "(wt.)". Support for these amendments can be found in the specification at page 9, lines 11-15 of the specification.

Claims 19, 39, and 56 have been amended to correct a typographical error. The spelling of the term "nonsteroidal" has been corrected from the incorrect spelling "nonsterodial."

No new matter has been added by these amendments; therefore, Applicants respectfully request that examination continue on the claims amended herewith. No new Claims fee is due.

Rejection under 35 USC §112

The Examiner rejected Claims 11, 12, 35, 36, 52, and 53 under 35 USC §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. The amendments herein to Claims 11, 12, 35, 36, 52, and 53 obviate the Examiner's rejection. Reconsideration and removal of the rejection is therefore respectfully requested.

Rejection under 35 USC §102(b)

The Examiner rejected Claims 1-17, 19-22, and 26-59 under 35 USC §102(b) as allegedly being anticipated by US 5,904,929 issued to Uekama *et al.* This rejection is respectfully traversed.

Uekama *et al.* discloses a pharmaceutical composition comprising (1) a per acylated cyclodextrin as a solubilizing agent and (2) a drug. *See* col. 2, lines 41-44. Uekama *et al.* also discloses that the pharmaceutical compositions can contain additional additives, examples of which include polymeric materials that are used as "physical property improvers." *See* col. 6,

lines 35-40; 51-69. Other polymers disclosed in Uekama *et al.* are used as substrates, such as a transdermal patch.

In contrast, the amended claims recite a carrier polymer with the inclusion complex incorporated therein. That is, the carrier polymer recited in the claims acts as a matrix. As used in Uekama *et al.*, "polymer" means only an additive that is added to the inclusion complex or substrate on which the inclusion complex is deposited. The reasonable reading of Uekama *et al.* is that polymers are optional ingredients used to merely augment the physical properties of the inclusion complex. *See* col. 6, lines 35-40. No reasonable reading of Uekama *et al.* would show a carrier polymer disclosed therein. Because Uekama *et al.* does not disclose compositions where a polymer is used as a carrier and the inclusion complex is incorporated into the carrier polymer, the amended claims are novel over this reference.

Rejection under 35 USC §103(a)

The Examiner rejected Claims 1-22 and 26-59 under 35 USC §103(a) as allegedly being obvious over Uekama *et al.* This rejection is respectfully traversed.

A summary of Uekama *et al.* is given above. And upon reasonable consideration of this reference, the skilled artisan would find absolutely no suggestion or motivation to prepare and/or use compositions whereby an inclusion complex is incorporated into a carrier polymer. As previously noted, the polymers disclosed in Uekama *et al.* are optional additives used to enhance the properties of the compositions described therein. Uekama *et al.* further discloses polymer substrates upon which an inclusion complex can be deposited (*see* Examples section). Neither of these teachings regarding polymers would suggest to the skilled artisan compositions and devices as those recited in the amended claims. Accordingly, the amended claims are not obvious over this reference.

The Examiner rejected Claims 1-22 and 26-59 under 35 USC §103(a) as allegedly being obvious over Uekama *et al.* in view of US 6,616,650 issued to Rowe. This rejection is respectfully traversed.

The failure of Uekama *et al.* to render the present invention obvious is discussed above. And the inclusion of Rowe to arrive at the present rejection does not remedy the inadequacy of the prior rejection with Uekama *et al.* alone. That is, Rowe does not disclose or suggest an inclusion complex incorporated within a carrier polymer.

Specifically, Rowe relates to the delivery of a therapeutic agent to an internal tissue site by advancing a catheter into a patient to where the catheter balloon portion carries the therapeutic agent, usually mixed with a controlled release carrier for the agent. Examples of controlled release carriers are disclosed at column 2, line 59 to column 3, line 3 of Rowe. While cyclodextrin is listed as a suitable controlled release carrier, as are various polymers, nowhere is there a disclosure or teaching of a cyclodextrin inclusion complex incorporated into a carrier polymer, as recited in the amended claims. Indeed, Rowe only teaches that a drug and a controlled release carrier are positioned on the outer surface of a lateral wall of a catheter balloon (col. 2, lines 38-41). Thus, Uekama *et al.* and Rowe, whether taken alone or in combination, do not suggest the incorporation of a cyclodextrin inclusion complex within a carrier polymer and, therefore, do not render the amended claims obvious.

The Examiner rejected Claims 1-22 and 26-59 under 35 USC §103(a) as allegedly being obvious over Uekama *et al.* in view of US 5,624,411 issued to Tuch. This rejection is respectfully traversed.

The failure of Uekama *et al.* to render the present invention obvious is discussed above. And the use of Tuch, like the use of Rowe, to arrive at the present rejection does not remedy the inadequacies of the prior rejections. In particular, Tuch does not disclose or suggest an inclusion complex incorporated within a carrier polymer.

Tuch discloses an intravascular stent with a coating that includes a polymer and a drug on the body of a stent, specifically, on its tissue-contacting surface. Tuch modulates the delivery of the drug from the stent by manipulating the layering of a polymeric coating deposited thereon. It is clear when one considers the entire disclosure of Tuch that the polymers mentioned therein serve the purpose of adhering a drug to the surface face of a stent. For example, Tuch, beginning at column 5, line 55, states:

> The ratio of therapeutic substance to polymer in the solution will depend on the efficacy of the polymer in *securing* the therapeutic substance onto the stent and the rate at which the coating is to release the therapeutic substance to the tissue of the blood vessel. More polymer may be needed if it has relatively poor efficacy in *retaining* the therapeutic substance on the stent. (emphasis added)

Thus, the polymers disclosed in Tuch are not carrier polymers where an inclusion complex is incorporated therein, but are instead used to affix a drug to the surface of a stent. Nothing in

Tuch can be taken to teach or suggest the incorporation of a therapeutic agent into a polymer, much less the incorporation of an inclusion complex into a carrier polymer.

Further, when lodging this rejection, the Examiner stated that it would have been obvious to prepare a drug eluting stent from a polymer and "*apply* a solution of an acylated cyclodextrin/drug inclusion complex to *the surface*" (emphasis added). This statement assumes that the present invention merely involves the application of an inclusion complex to a polymer surface. Instead, the amended claims recite the *incorporation* of an inclusion complex into a carrier polymer. So even assuming, *arguendo*, that Tuch would have suggested the application of an inclusion complex onto a polymer surface (which is does not), the result would not have produced the present invention. Accordingly, the rejection under 35 USC §103(a) should be withdrawn.

The Examiner rejected Claims 1-22 and 26-59 under 35 USC §103(a) as allegedly being obvious over Uekama *et al.* in view of US 5,865,792 issued to Ledger *et al.* and further in view of US 5,817,332 issue to Urtti *et al.* This rejection is respectfully traversed.

As noted, Uekama *et al.* does not disclose or suggest an inclusion complex incorporated within a carrier polymer. The further addition of Ledger *et al.* and Urtti *et al.* to the rejection still does not render the present invention obvious at least because these references also fail to disclose the incorporation of an inclusion complex into a carrier polymer.

Specifically, Ledger *et al.* discloses a composition and product for use in an electrotransport device. The composition includes an ionized drug, an anti-inflammatory agent, and a solvent. Examples of solvents disclosed in Ledger *et al.* include cyclodextrin, among many other materials. Ledger *et al.* states that the solvent (*e.g.*, water and cyclodextrin) and drug are placed into a reservoir (*see e.g.*, col. 3, lines 12-20). By applying a current to the device, solvated drug in the reservoir can be transdermally delivered to a patient.

Ledger *et al.* does not render the present invention obvious at least because there is no disclosure, teaching, or suggestion to incorporate an inclusion complex into a carrier polymer, as recited in the amended claims. The only mention of a drug with a cyclodextrin is in a reservoir of an electrotransport device. There is simply no motivation in Ledger *et al.* to incorporate an inclusion complex into a carrier polymer.

Moreover, the entire disclosure of Ledger *et al.* is based on the principle of electrotransport where an ionic drug having sufficient potential can be driven into a patient by an applied electric current. If one were to incorporate an ionic drug (or even an inclusion complex comprising an ionic drug) into a carrier polymer, the drug's ionic potential would likely be diminished by the surrounding carrier polymer. As such, the electrotransport device and methods of Ledger *et al.* would not be able to electrically deliver a drug (or it would at least be more difficult) if it were part of an inclusion complex incorporated into a carrier polymer. Thus, the skilled artisan considering Ledger *et al.* would not have been motivated to incorporate an inclusion complex into a carrier polymer, whether based on the teachings of Uekama *et al.* or otherwise.

Urtti *et al.* discloses a transdermal drug delivery system that includes a reservoir comprising a therapeutic agent in ionized form, a pH adjusting agent, and a cyclized polysaccharide (*e.g.*, cyclodextrin). The reservoir wall can be made of a polymer. As such, the polymer disclosed in Urtti *et al.* is not a carrier polymer, as recited in the amended claims. In other words, the drug and cyclodextrin in Urtti *et al.* are encapsulated by a polymeric wall to form a reservoir; they are not incorporated within a carrier polymer. There is no teaching, suggestion, or motivation to incorporate an inclusion complex into a carrier polymer in Urtti *et al.*

Since none of Uekama *et al.*, Ledger *et al.*, and Urtti *et al.* disclose or suggest a carrier polymer with an inclusion complex therein, the amended claims are patentable over these references.

CONCLUSION

Pursuant to the above amendments and remarks, reconsideration and allowance of the pending application is believed to be warranted. The Examiner is invited and encouraged to directly contact the undersigned if such contact may enhance the efficient prosecution of this application to issue.

No fee is believed to be due; however, the Commissioner is hereby authorized to charge any additional fees that may be required, or credit any overpayment to Deposit Account No. 14-0629.

Respectfully submitted,
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CERTIFICATE OF MAILING UNDER 37 CFR § 1.8

I hereby certify that this correspondence and the documents mentioned therein are being deposited with the United States Postal Service in an envelope addressed to: MAIL STOP AMENDMENT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA. 22313-1450, on the date indicated below

Christopher L. Curfman — Date: September 29, 2006